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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/400,365	09/20/1999	FADY T. CHARBEL	76461	3361

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WELSH & KATZ, LTD
120 S RIVERSIDE PLAZA
22ND FLOOR
CHICAGO, IL 60606

EXAMINER	
JONES, HUGH M	
ART UNIT	**PAPER NUMBER**
2128	

DATE MAILED: 01/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/400,365	CHARBEL ET AL.	
	Examiner	Art Unit	
	Hugh Jones	2128	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-7,9-13,15-18,20-22,52-54 and 56-65* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-7,9-13,15-18,20-22, 52-54, 56-65* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☑ The drawing(s) filed on 9/20/1999 is/are: a)☐ accepted or b)☑ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Introduction

1. Claims 1-2, 5-7, 9-13, 15-18, 20-22, 52-54, 56-65 of U. S. Application 09/400,365 filed on 20-September-1999, are pending. This action is responsive to September 7, 2004.

Drawings

2. Figures 2, 4-7, 10-13, 21, 23 should be designated by a legend such as --Prior Art-- because only that which is old is illustrated. See MPEP § 608.02(g). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance. Figures 2, 7, 21, 23 are well known in the prior art. Figures 4-6, 10-13 appear to be copyrighted by the Canvas group at the University of Illinois.

Oath/Declaration

3. The substitute Declaration appears to be defective for the following reasons:

- it does not appear to include a correct listing of inventors. The substitute Declaration makes a priority claim (via a Continuation-In-Part) to US Provisional Application 60/073,580. However, it appears only Clark, Zhao and Charbel authored the non-patent literature in the priority application;

at the same time there are two other inventors listed for the instant application;

- The University of Illinois and the Department of Neurosurgery have copyrighted the non-patent literature in the priority application. Please clarify the rights, if any, of the University of Illinois in this matter. Furthermore, please provide the names of other members of the Canvas group.

Priority

4. Applicants state (page 11, paper # 21) that:

> "In a previous office action, the Kamm reference (U.S. Patent 6,117,087) was properly withdrawn as a prior art reference in the view of the effective filing date of the then pending claims of February 3, 1998. Applicant neither admits nor denies the prior art status of the Kamm reference, but hereby withdraws the claim to priority based on the February 3, 1998 filing date for the presently pending claims as amended. ... Applicants expressly reserves the right to reassert the claim for priority based upon the Feburary 3, 1998 filing date in this or a later-filed application."

5. The Examiner requested (paper # 23) unambiguous clarification of Applicant's filing date so that the Examiner can properly examine the application in a compact and timely fashion. It is noted that the 102(e) rejection based on Kamm was withdrawn in view of Applicant's claim to the 2/3/1998 priority. Applicants consequently withdrew the

claim to priority after the 102(e) prior art was withdrawn. Hence, the Kamm rejection was reasserted (paper # 23).

6. Following the reassertion of the Kamm rejection, Applicants have again reversed their position and now reassert their claim.

7. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-3, 5-7, 9-13, 15-18, 20-28, 52-55 of this application. 10. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

8. Application 09/400,365 is a Continuation-In-Part of U.S. Patent 09/243,870 which claims priority to Provisional application 60/073,580.

9. The Examiner will assume, for purposes of examination that the the effective filing date of the U. S. Application 09/400,365 is 9/20/1999 because Applicants do not have 112 support in the '870 specification or in the provisional application for the claims in the instant ('365) application.

10. MPEP section 706.02 recites:

"DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION

The effective filing date of a U.S. application may be determined as follows:

(A) If the application is a continuation or divisional of one or more earlier U.S. applications and if the requirements of 35 U.S.C. 120 have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.

(B) If the application is a continuation-in-part of an earlier U.S. application, ***any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.*** *Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application.*"

11. The Continuation-In-Part (the '365 application) is not an incorporation by reference of the parent application by the Continuation-In-Part, because Applicants did not incorporate the parent. Furthermore, the parent application ('870) itself did not incorporate by reference the provisional application. In fact, the '870 application did not claim priority to the provisional application until after the filing date of the '870 application – where it was amended to be a "Continuation-In-part" of the Provisional Application.

12. In any case, such an incorporation would constitute new matter and defeat the purpose of the conversion of the '870 application into a Continuation-In-Part. Therefore, only claims which are *directed solely* to *common disclosure* between the '365 and '870 specifications, and for which there is 112(1) support in the

parent specification, are eligible for the priority of the '870 application. See the MPEP

> "Any claim in a continuation-in-part application which is directed solely to subject matter adequately disclosed under 35 U.S.C. 112 in the parent nonprovisional application is entitled to the benefit of the filing date of the parent nonprovisional application. However, if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent nonprovisional application, but which was first introduced or adequately supported in the continuation-in-part application such a claim is entitled only to the filing date of the continuation-in-part application; In re Chu, 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995); Transco Products, Inc. v. Performance Contracting Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); In re Von Lagenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972); and Chromalloy American Corp. v. Alloy Surfaces Co., Inc., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972)."

13. Note MPEP section 2217, which recites in part:

> "The statement applying the prior art may, where appropriate, point out that claims in the patent for which reexamination is requested are entitled only to the filing date of the patent and are not supported by an earlier foreign or United States patent application whose filing date is claimed. ***For example, the effective date of some of the claims in a patent which resulted from a continuing application under 35 U.S.C. 120 could be the filing date of the continuing application since those claims were not supported in the parent application. Therefore, intervening patents or printed publications are available as prior art.*** See In re Ruscetta, 255 F.2d 687, 118 USPQ 101 (CCPA 1958), In re van Langehoven, 458 F.2d 132, 173 USPQ 426 (CCPA 1972). See also MPEP 201.11."

14. The Examiner, again respectfully, refers Patent owners to MPEP section 706.02 which recites:

> "DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION

> The effective filing date of a U.S. application may be determined as follows:
>
> (A) If the application is a continuation or divisional of one or more earlier U.S. applications and if the requirements of 35 U.S.C. 120 have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.
>
> *(B) If the application is a continuation-in-part of an earlier U.S. application,* ***any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.*** *Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application."*

15. The Kamm rejection is therefore maintained.

Claim Rejections - 35 USC § 103

16. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

17. Before setting forth the rejection below, a short discussion of the art is in order. Applicant's IDS has set forth the following references that this examiner considers to be pertinent in the present application:

a. "Predictive Value of a Computerized Model for the Cerebral Circulation," (Poster Abstract) a presentation apparently made at the 44th Annual Meeting of Congress of Neurological Surgeons in October of 1994 [previously dubbed as "Charbel #2" in the prior Office Action]; and

b. "Validation and Clinical Potential of a Computerized Model of the Cerebral Circulation," (Poster Abstract) a presentation apparently made at the first Annual Meeting of the Joint Section on Cerebrovascular Surgery of the American Association of Neurological Surgeons and the Congress of Neurological Surgeons in January of 1996 [previously dubbed as "Charbel #1" in the prior Office Action.

18. Looking at the authors of these presentations, it is apparent that two of the named inventors in the present application were working on the materials in at least two of these presentations more than a year prior to the filing of the provisional application from which the current application depends (i.e., February 3, 1998). Furthermore, it is apparent from reading the abstracts that the work presented in 1996 [previously dubbed Charbel #1] was an extension of the work presented in 1994 [previously dubbed Charbel #2]. More specifically, the abstract from the 1994 presentation states, in part, "[W]e find the predictive value of this model promising. In vivo validation is currently

underway." Unsurprisingly, the presentation made in 1996 is a "direct in vivo validation of the [computer] model." Though the authors (i.e., the "inventive entities") of these presentations are not exactly the same, three of the listed authors remained consistent (i.e., Charbel, Clarke, Ausman). Consequently, these two presentations are hereby considered to be one "teaching" (i.e., the 1996 validation procedures used the computer modeling disclosed in the 1994 presentation).

19. The Examiner's attempt to verify this inference in a Rule 105 request in a previous office Action did not produce any more guidance from the applicant. However, due to the direct correlation between the abstracts themselves, it is this examiner's belief that the two presentations are directed to the same computer simulation model disclosed in the 1994 presentation. Thus, it is on this proposition that the following rejection is based. For convenience, these two presentations will be referred to simply as "Charbel et al." hereinafter.

20. Claims 1-2, 9-13, 20-22, 56-65 are rejected under 35 U.S.C. 103 (a) as being unpatentable over [Charbel et al., as discussed above, or Kamm et al. or Kufahl t al. (1985 - of record)], in view of any of [Clark et al. (1989, pp. 217-230 - of record) or Himwich et al. (1965, pp. 164-172 - of record) or Himwich et al. (1974 - of record)].

21. Charbel et al. discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any

multivesseled network configuration, including the Circle of Willis, as well as surgical anatomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery to obtain computerized model of the cerebral circulation and its concurrent simulation results. The simulation includes forcing the model by one or more pressure- or flow-time signatures. (1994 presentation abstract: p. 166, §27.) The computerized model is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" that is "reconfigured to include stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy.". Note that the title is "*Predictive* value of a computerized model of the cerebral circulation". (1996 presentation abstract: p. 113, col. 1, Par. 1.) The calculated flow and the measured flow are then compared to validate the accuracy of the computer model to the actual patient (i.e., to correct for any discrepancies observed between the predicted and actual values). (1996 presentation abstract: p. 113, col. 2, lns. 11-15.).

22. Kamm et al. disclose a method and apparatus for deriving a physiological description and clinically-useful data reboarding the cardiovascular system of an individual subject. The method includes obtaining a measurement sample associated with cardiovascular flow and utilizing a model, which may be distributed and/or non-

linear to derive a description and data. The model generates and uses functions of source parameters and may, in an embodiment, match measurement samples against a library of stored predicted samples. A best-matching, predicted sample may then be associated with a measurement sample. An apparatus is provided which, according to an embodiment, includes an input for obtaining a measurement sample, a processor to derive the description and data, and an output. The apparatus may also include a digital storage medium to store a library of predicted samples. In particular, Kamm et al. disclose a computerized modeling simulation system that takes a general model of an arterial circulatory network and modifies the general model with specific parameters of a patient for a more accurate model/simulation specific for that patient as recited in the claims. See at least col. 1, lines 25-26, 36-47, 60-65; col. 2, lines 4-6; col. 3, lines 6-10, 35-37, 45-68; col. 4, lines 1-6, 23-28; col. 8, lines 49-50, 54-56; col. 9, lines 10-11; col. 10, lines 33-35, 49-54; col. 13, lines 25-26.

23. Kufahl et al. (1985 – of record) disclose a circle of Willis simulation. In particular, they disclose a one-dimensional numerical (finite-difference) model of the arterial network surrounding the circle of Willis which is based on the full Navier-Stokes and conservation of mass equations generalized for distensible vessels. The present model assumes an elastic wall defined by a logarithmic pressure-area relation obtained from the literature. The viscous term in the momentum equation is evaluated using the slope of a Karman-Pohlhausen velocity profile at the vessel boundary. The afferent vessels

(two carotids and two vertebrals) are forced with a canine physiologic pressure corresponding to an aortic site. The network associated with each main efferent artery of the circle is represented by a single vessel containing an appropriate amount of resistance so that the mean flow through the system is distributed in accordance with the weight of brain irrigated by each vessel as determined from a steady flow model of the same network. This resistance is placed a quarter wave-length downstream from the heart to insure proper reflection from the terminations, where the quarter wavelength is determined using the frequency corresponding to the first minimum on an input impedance-frequency diagram obtained at the heart. Computer results are given as time histories of pressure and flow at any model nodal point starting from initial conditions of null flow and constant pressure throughout the model. Variations in these pressure and flow distributions caused by the introduction of pathologic situations into the model illustrate the efficacy of the simulation and of the circle in equalizing and redistributing flows in abnormal situations. See the following sections:

- Methodology: RC models;
- Governing Equations: mass balance, momentum balance;
- Boundary Equation: note figure 5;
- Initial Conditions;
- Cerebral Circulation Model.

24. The base references do not expressly disclose calibrating the flow resistance by using a ratio of measured and calculated flows.

25. **Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974)** disclose the use of corrections or fitting parameters to calibrate the blood flow resistance to correspond to individual differences between patients. See Clark 1989 at page 220; Himwich 1965 at page 167; Himwich 1974 at section D (Resistance Adjustment).

26. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the base reference to include calibrating the flow resistance by using a ratio of measured and calculated flows for the following reasons. Any realistic simulation of blood flow in humans must account for individual differences in blood flows. The blood flow models are based upon equivalent RC circuit network models. A particular blood flow is associated with each simulation including the simulation parameters. Fitting parameters are required change the flow resistance in the model to ensure that the blood flow corresponds to "real-life" blood flows in different individuals. The use of the "ratios" is merely the implementation of fitting parameters to calibrate the blood flow to correspond to a particular set of circumstances.

27. Claims 5-7, are rejected under 35 U.S.C. 103 (a) as being unpatentable over Charbel et al., or Kamm et al., as discussed above, in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich t al., 1974)

and in further view of any of Karplus or Foutrakis, both previously cited by the examiner.

28. Charbel et al. discloses a computer program and method for simulating surgical procedures on a patient that alters circulation systems. The computer program is for any multivesseled network configuration, including the Circle of Willis, as well as surgical anatomoses supplied to the vessels. The computer program applies one-dimensional, explicit, finite-difference algorithm based on a conservation of mass equation, a Navier-Stokes momentum equation, and an equation of state relating local pressure to size of artery to obtain computerized model of the cerebral circulation and its concurrent simulation results. The simulation includes forcing the model by one or more pressure- or flow-time signatures. (1994 presentation abstract: p. 166, §27.) The computerized model is specifically tailored to "any distensible vessels of various shapes, lengths and configurations" that is "reconfigured to include stenoses, bypasses and natural or imposed anatomoses" (i.e., surgical perturbations) thereby "reproducing each patient's individual anatomy." (1996 presentation abstract: p. 113, col. 1, Par. 1.) The calculated flow and the measured flow are then compared to validate the accuracy of the computer model to the actual patient (i.e., to correct for any discrepancies observed between the predicted and actual values). (1996 presentation abstract: p. 113, col. 2, lns. 11-15.).

29. Kamm et al. disclose a method and apparatus for deriving a physiological description and clinically-useful data reboarding the cardiovascular system of an

individual subject. The method includes obtaining a measurement sample associated with cardiovascular flow and utilizing a model, which may be distributed and/or non-linear to derive a description and data. The model generates and uses functions of source parameters and may, in an embodiment, match measurement samples against a library of stored predicted samples. A best-matching, predicted sample may then be associated with a measurement sample. An apparatus is provided which, according to an embodiment, includes an input for obtaining a measurement sample, a processor to derive the description and data, and an output. The apparatus may also include a digital storage medium to store a library of predicted samples. In particular, Kamm et al. disclose a computerized modeling simulation system that takes a general model of an arterial circulatory network and modifies the general model with specific parameters of a patient for a more accurate model/simulation specific for that patient as recited in the claims. See at least col. 1, lines 25-26, 36-47, 60-65; col. 2, lines 4-6; col. 3, lines 6-10, 35-37, 45-68; col. 4, lines 1-6, 23-28; col. 8, lines 49-50, 54-56; col. 9, lines 10-11; col. 10, lines 33-35, 49-54; col. 13, lines 25-26.

30. The cited art discloses the recited invention as discussed above. However, said art does not teach how the specific parameters are collected, i.e., obtaining boundary measurements (e.g., diameter of the vessel and tracing ends of the vessel) using image/pixel analysis to determine the measurements of the vessels of the living subject. Karplus, previously cited and applied in a prior office Action, teaches obtaining

boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (p. 38, §3.2) Foutrakis, previously cited and applied in a prior Office Action, teaches obtaining boundary and cross-section information of specified vessels using MRI technology for the purpose of inputting the gathered information into a circulation simulator for generating a specific simulation result for a specific patient. (Abstract; p. 4; Figure 7; p. 12) It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Magnetic Resonance Imaging technology to obtain the specific parameters of a specific vessel as taught by Karplus and Foutrakis to be used in the simulation as taught by the base references because the base references already teach tailoring a simulation using specific parameters of a vessel of a patient and Karplus/Foutrakis both teach it is well know to obtain such information using MRI technology in the manner recited.

31. Claims 15-18, 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charbel et al., or Kamm et al., as applied above, in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974) and in further view of Charbel et a1. (1997 presentation abstract), cited by the Applicant.

32. As to claims 15, 52, and 56, the cited art discloses the recited invention as discussed above. In particular, said art specifically teaches that direct flow

measurements were obtained. However, the cited art does not specifically teach that PCMRA (Phase Contract Magnetic Resonance Angiography) flow measurement techniques were used.

33. Charbel et al. ("Phase Contract MR Flow Measurement System Using Volumetric Flow Contrainted Image Interpolation and Color Coded Image Visualization", Poster Abstract of a presentation made at the 47th Annual Meeting of Congress of Neurological Surgeons in September/October of 1997) discloses that PCMRA was available in 1997 to measure blood flow in a patient. Moreover, various other non-intrusive flow measurement systems were already available at the time the invention was made (e.g., Doppler). Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to have used PCMRA to obtain the flow measurement since it was known to one of ordinary skill in the art that non-invasive measurement techniques were available, and PCMRA was purported to provide a more accurate flow measurement result than the other options as taught in Charbel et al. (1997 presentation abstract).

34. As to claims 16-18, Charbel et al. (1997 presentation) teaches that PCMRA can also be used to obtain cross-section measurements as well. (1997 presentation abstract: p. 377, Introduction, lines 4-6). As to localizing and tracing three dimensional images of a vessel to obtain the measure, these steps are inherent in obtaining vessel measurements using image analysis (See Karplus and Foutrakis, cited and applied

above) and therefore is considered to be inherent in Charbel et al. (1997 presentation abstract).

35. Claims 53 and 54 are rejected under 35 U.S.C. 103 (a) as being unpatentabl over [Charbel et al. or Kamm et al. or Kufahl et – 1985 – of record)] in view of any of Clark et al. (1989, pp. 217-230) or Himwich et al. (1965, pp. 164-172) or Himwich et al., 1974) and in further view of either Karplus or Ortega ("Predicting Cerebral Aneurysms with CFD"), previously cited.

36. The cited art teaches the recited invention as applied above. Though said art teaches obtaining flow measurement, it does not teach that the flow measurements were obtained by Doppler measurements.

37. Karplus, as discussed above, teaches using Doppler flow measurements to correct and validate simulation results. (p. 40, col. 2, Par. 4)

38. Ortega discloses using Doppler flow measurements to be used in Computational Fluid Dynamics simulation (CFD).

39. It would have been obvious for one of ordinary skill in the art at the time of the invention to have used Doppler technology to correct and validate simulation results as taught by Karplus/Ortega in the simulation as taught by Charbel et al. or Kamm et al. or Kufahl et al. because Karplus/Ortega teaches that such correction/validation techniques using Doppler is well known to one of ordinary skill in the art to verify predicted results with actual results and non-invasive technology is always preferred.

***Response to Arguments* (Response of September 7, 2004)**

40. Applicant's arguments filed 9/07/2004 have been fully considered but they are not persuasive.

***Response to Arguments – Objection to the Figures* (pg. 9)**

41. Applicant's arguments filed 9/07/2004 have been fully considered but they are not persuasive. Applicants have merely offered their beliefs, but have cited no court decisions. Figures 2, 7, 21, 23 are well known in the prior art. Figures 4-6, 10-13 appear to be copyrighted by the Canvas group at the University of Illinois.

***Response to Arguments – Objection to the Declaration* (pg. 9)**

42. Applicant's arguments filed 9/07/2004 have been fully considered but they are not persuasive. Applicants have not adequately responded to the specifics of the objection. The substitute Declaration appears to be defective for the following reasons:

- it does not appear to include a correct listing of inventors. The substitute Declaration makes a priority claim (via a Continuation-In-Part) to US Provisional Application 60/073,580. However, it appears only Clark, Zhao and Charbel authored the non-patent literature in the priority application; at the same time there are two other inventors listed for the instant application;

- The University of Illinois and the Department of Neurosurgery have copyrighted the non-patent literature in the priority application. Please clarify the rights, if any, of the University of Illinois in this matter. Furthermore, please provide the names of other members of the Canvas group.

Response to Arguments – Claim for Priority (pg. 10)

43. Applicant's arguments filed 9/07/2004 have been fully considered but they are not persuasive. The Examiner first requests clarification of the meaning of the word "***substantially***", as used in Applicant's arguments on page 10 of the response.

44. The Examiner has reviewed the sections cites as providing 112 support. The Examiner, respectfully, is not persuaded. Applicants have merely indicated that support is somewhere within the nine pages, but have provided no specific showing of support.

45. Applicants, respectfully, have not addressed most of the issues raised by the Examiner relating to priority. The issues are therefore repeated for Applicants to consider.

46. Applicants state (page 11, paper # 21) that:

> "In a previous office action, the Kamm reference (U.S. Patent 6,117,087) was properly withdrawn as a prior art reference in the view of the effective filing date of the then pending claims of February 3, 1998. Applicant neither admits nor denies the prior art status of the Kamm reference, but hereby withdraws the claim to priority based on the February 3, 1998 filing date for

the presently pending claims as amended. ... Applicants expressly reserves the right to reassert the claim for priority based upon the Feburary 3, 1998 filing date in this or a later-filed application."

47. The Examiner requested (paper # 23) unambiguous clarification of Applicant's filing date so that the Examiner can properly examine the application in a compact and timely fashion. It is noted that the 102(e) rejection based on Kamm was withdrawn in view of Applicant's claim to the 2/3/1998 priority. Applicants consequently withdrew the claim to priority after the 102(e) prior art was withdrawn. Hence, the Kamm rejection was reasserted (paper # 23).

48. Following the reassertion of the Kamm rejection, Applicants have again reversed their position and now reassert their claim.

49. Applicant's claim for domestic priority under 35 U.S.C. 119(e) is acknowledged. However, the provisional application upon which priority is claimed fails to provide adequate support under 35 U.S.C. 112 for claims 1-3, 5-7, 9-13, 15-18, 20-28, 52-55 of this application.

50. The later-filed application must be an application for a patent for an invention which is also disclosed in the prior application (the parent or original nonprovisional application or provisional application); the disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

51. Application 09/400,365 is a Continuation-In-Part of U.S. Patent 09/243,870 which claims priority to Provisional application 60/073,580.

52. The Examiner will assume, for purposes of examination that the the effective filing date of the U. S. Application 09/400,365 is 9/20/1999 because Applicants do not have 112 support in the '870 specification or in the provisional application for the claims in the instant ('365) application.

53. MPEP section 706.02 recites:

"DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION

The effective filing date of a U.S. application may be determined as follows:

(A) If the application is a continuation or divisional of one or more earlier U.S. applications and if the requirements of 35 U.S.C. 120 have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.

(B) If the application is a continuation-in-part of an earlier U.S. application, ***any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.*** *Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application."*

54. The Continuation-In-Part (the '365 application) is not an incorporation by reference of the parent application by the Continuation-In-Part, because Applicants did not incorporate the parent. Furthermore, the parent application ('870) itself did not incorporate by reference the provisional application. In fact, the '870 application did not claim priority to the provisional application until after

the filing date of the '870 application – where it was amended to be a "Continuation-In-part" of the Provisional Application.

55. In any case, such an incorporation would constitute new matter and defeat the purpose of the conversion of the '870 application into a Continuation-In-Part. Therefore, only claims which are *directed solely* to *common disclosure* between the '365 and '870 specifications, and for which there is 112(1) support in the parent specification, are eligible for the priority of the '870 application. See the MPEP

> "Any claim in a continuation-in-part application which is directed solely to subject matter adequately disclosed under 35 U.S.C. 112 in the parent nonprovisional application is entitled to the benefit of the filing date of the parent nonprovisional application. However, if a claim in a continuation-in-part application recites a feature which was not disclosed or adequately supported by a proper disclosure under 35 U.S.C. 112 in the parent nonprovisional application, but which was first introduced or adequately supported in the continuation-in-part application such a claim is entitled only to the filing date of the continuation-in-part application; In re Chu, 66 F.3d 292, 36 USPQ2d 1089 (Fed. Cir. 1995); Transco Products, Inc. v. Performance Contracting Inc., 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994); In re Von Lagenhoven, 458 F.2d 132, 136, 173 USPQ 426, 429 (CCPA 1972); and Chromalloy American Corp. v. Alloy Surfaces Co., Inc., 339 F. Supp. 859, 874, 173 USPQ 295, 306 (D. Del. 1972)."

56. Note MPEP section 2217, which recites in part:

> "The statement applying the prior art may, where appropriate, point out that claims in the patent for which reexamination is requested are entitled only to the filing date of the patent and are not supported by an earlier foreign or United States patent application whose filing date is claimed. ***For example, the effective date of some of the claims in a patent which resulted from a continuing application under 35 U.S.C. 120 could be the***

> ***filing date of the continuing application since those claims were not supported in the parent application. Therefore, intervening patents or printed publications are available as prior art.*** See In re Ruscetta, 255 F.2d 687, 118 USPQ 101 (CCPA 1958), In re van Langehoven, 458 F.2d 132, 173 USPQ 426 (CCPA 1972). See also MPEP 201.11."

57. The Examiner, again respectfully, refers Patent owners to MPEP section 706.02 which recites:

> "DETERMINING THE EFFECTIVE FILING DATE OF THE APPLICATION
> The effective filing date of a U.S. application may be determined as follows:
>
> (A) If the application is a continuation or divisional of one or more earlier U.S. applications and if the requirements of 35 U.S.C. 120 have been satisfied, the effective filing date is the same as the earliest filing date in the line of continuation or divisional applications.
>
> *(B) If the application is a continuation-in-part of an earlier U.S. application,* ***any claims in the new application not supported by the specification and claims of the parent application have an effective filing date equal to the filing date of the new application.*** *Any claims which are fully supported under 35 U.S.C. 112 by the earlier parent application have the effective filing date of that earlier parent application."*

58. The Kamm rejection is therefore maintained.

Response to Arguments – 103 Rejections (pp. 10-12)

59. Applicant's arguments filed 9/07/2004 have been fully considered but they are not persuasive.

60. The Kamm et al. rejection is maintained for the reasons presented earlier.

61. Applicants argument relating to the meaning of "vascular remodeling procedures" is persuasive in view of the declarartion. However, this does not detract from the

teachings of the the Charbel references, as applied to the claims. Note, for example, that the first paragraph recites, "*Multiple surgical options can be simulated for each patient* and the optimal one is thus determined".

62. In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

63. Any inquiry concerning this communication or earlier communications from the examiner should be:

directed to:

Dr. Hugh Jones telephone number (703) 305-0023, Monday-Thursday 0830 to 0700 ET,
or the examiner's supervisor, Kevin Teska, telephone number (703) 305-9704.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, telephone number (703) 305-3900.

mailed to:

Commissioner of Patents and Trademarks
Washington, D.C. 20231

or faxed to:

(703) 308-9051 (for formal communications intended for entry) ***or***
(703) 308-1396 (for informal or draft communications, please label "*PROPOSED*" or "*DRAFT*").

Dr. Hugh Jones

Primary Patent Examiner

January 9, 2005